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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,989	08/21/2001	Michael H.B. Stowell	06618-045002	8355

7590

01/30/2003

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EXAMINER

MULLIS, JEFFREY C

ART UNIT

PAPER NUMBER

1711

DATE MAILED: 01/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/934,989

Applicant(s)

STOWELL ET AL.

Examiner

Jeffrey C. Mullis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,3,5,6 and 8 is/are allowed.
- 6) ☒ Claim(s) 1,4,9,10 and 12-16 is/are rejected.
- 7) ☒ Claim(s) 11 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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All previous rejections and/or objections have been withdrawn. All remaining rejections follow.

6-03  
Claim 8 contains a number of instances in which "Sl" appears, i.e. a dot over the i in "Si" appears to have been run into the rest of the letter such that it appears to be an l. Correction is requested.

11  
It is requested that a period be placed at the end of claim 17.

M  
Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The term "formed elements" in claim 4 is not art recognized and is therefore unclear.

M  
Claims 4 and 9-17 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 4 recites the limitations "formed elements" and "membrane is associated with an acidic compound capable of modifying the pH of the fluid" while claim 9 recites "stabilizing the lipid vesicle" and since such limitations were not present in the specification as filed, these limitations are new matter.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10 and 13-16 are rejected under 35 U.S.C. §

*du<sup>e</sup>* 102(b) as being anticipated by Lanquetin (French Patent 2642305).

*4.03*  
*/C-03*  
Lanquetin discloses "liposomes" containing phospholipids in an organosilicon compound. Note the abstract. The organosilicon compound may contain methyltrisilanol at page 3 lines 15-20. Hyaluronic acid, a macromolecular compound may be encapsulated at page 3 lines 25-30. Since silanols are known to spontaneously condense and since the methyltrisilanol is multifunctional, it would reasonably appear to form cross-links inherently.

*d 9/2*  
*je*  
*M1, B-1*  
*6.03*  
Claims 1, 9 and 12-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nakamura et al. (Nippon Kagaku Kaishi (1990) (10) column 116-70).

Nakamura et al. disclose the production of "Micelle-like aggregates" by hydrolysis of tetramethoxysilane and octyltrimethoxysilane embraced by applicants' "silyl lipid". The dye appears to be encapsulated by the process also. Note the Abstract.

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Applicants' arguments filed 10-22-02 have been fully considered but they are not deemed to be persuasive.

Applicants argue that no new matter is added but have not pointed out support in the specification for their amendments.

Applicants allege that the Office action provides an "attachment for PTO-948". However this is incorrect. The cover letter of the Office action did not provide a check mark in the attachment for PTO-948. If applicants are requesting that the Draftsman review their drawings and that a PTO-948 then be provided, the Examiner will gladly talk to the Draftsman about providing a PTO-948. At present, however, there is no PTO-948 in the case.

It is noted the page numbers of Nakamura et al. on Form "PTO-892" in the case have been corrected to recite page numbers from 16-70.

Claims 11 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an

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additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Mullis whose telephone number is (703) 308-2820. The examiner can normally be reached on Monday-Friday from 9:30 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck, can be reached on (703) 308-2462. The fax phone number for this Group is before final (703) 872-9310 and after final (703) 8729311.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-2351.

J. Mullis:cdc

January 29, 2003

Priority Examiner  
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A handwritten signature in black ink, consisting of a large, stylized 'M' followed by a horizontal line and a small dash.